

September 8, 1999

DRAFT

AGENDA
BLOOD PRODUCTS ADVISORY COMMITTEE
64th Meeting - September 16-17, 1999
Bethesda Ramada Inn
8400 Wisconsin Avenue, Bethesda MD

Thursday, September 16, 1999

8:00 a.m. Statement of Conflict of Interest

8:05 a.m. Welcome and Opening Remarks

8:10 a.m. **Committee Updates**

- Summary of PHS Advisory Committee Meeting - Stephen Nightingale, M.D.
- Summary of Workshop on Donor Suitability: Blood Donor Deferral for History of Hepatitis - Robin Biswas, M.D.
- Summary of Guidance Document on Revised Precautionary Measures to Reduce the Possible Risk of Transmission of CJD and nvCJD by Blood and Blood Products - Mary Elizabeth Jacobs, Ph.D.
- Update on SENV Virus -Edward Tabor, M.D.
- Update on Status of Blood Regulations - Martin Ruta, J.D., Ph.D.
- HCV Lookback - Paul Mied, Ph.D
- Post-Donation Information Affecting Safety of Plasma Derivatives: Revised Algorithm - Edward Tabor, M.D.

9:30 a.m. ***Open Committee Discussion***

**I. Strategies for Increasing the Blood Supply -
Informational**

Introduction and Background - Captain Mary
Gustafson, Director, Division of Blood
Applications, OBRR

10:00 a.m. **OPEN PUBLIC HEARING**

10:30 a.m. **BREAK**

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11:00 a.m. ***Open Committee Discussion***

II. Nucleic Acid Testing of Blood Donors for Human Parvovirus B-19

- A. Introduction and Background - Thomas Lynch, Ph.D., Deputy Director, Division of Hematology, OBRR
- B. Presentation - Neal S. Young, M.D., NHLBI

11:30 a.m. **OPEN PUBLIC HEARING**

12 NOON ***Open Committee Discussion***

- C. FDA Perspective and Questions for the Committee
- D. Committee Discussion and Recommendations

1:00 p.m. **LUNCH**

2:00 p.m. **III. Antigen/Antibody Testing for Malaria - Informational**

- A. Introduction and Background - Chiang Syin, Ph.D., Division of Emerging Transfusion Transmitted Diseases
- B. Presentation - Freddie Poole, Scientific Reviewer, Microbiology Branch, DCLD, CDRH, ODE
- C. Presentation - Robert A. Gasser, Jr., M.D. Infectious Disease Officer, Walter Reed Army Institute of Research
- D. Presentation - Phuc Nguyen-Dinh, M.D., MPH Medical Officer, Centers for Disease Control and Prevention

3:00 p.m. **OPEN PUBLIC HEARING**

3:30 p.m. ***Open Committee Discussion***

- E. Committee Discussion and Recommendations

4:30 p.m. **Recess** (until 8:00 a.m. Friday, September 17, 1999)

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8:00 a.m. **Open Committee Discussion**

IV. Medical Device Panel Reclassification of HIV Drug Sensitivity Assays

- A. Introduction and Background - Andrew Dayton, M.D., Ph.D., Regulatory Scientist, Molecular Virology Branch, DETTD, OBRR
- B. Overview of Device Reclassification - Leonard Wilson, Chief, Regulatory Project Management Branch, Division of Blood Applications, OBRR
- C. Presentation - Douglas Mayers, M.D. Division Head, Infectious Diseases Henry Ford Hospital, Detroit, MI
- D. CDER Perspective - Jeff Murray, M.D., MPH, Medical Reviewer, DAVDP

10:00 a.m. **OPEN PUBLIC HEARING**

11:00 a.m. **BREAK**

12:30 Noon **Open Committee Discussion**

- E. Charge to the Committee - Executive Secretary, BPAC
- F. Committee Discussion and Recommendations

2:00 p.m. **ADJOURNMENT**